

Atty Dkt. No.: LIFE008
LFS-101
USSN: 09/593,827
Exhibit 1

CERTIFICATE OF FACSIMILE		
I hereby certify that this correspondence is being transmitted via facsimile to the U.S. Patent and Trademark Office at		
Typed or Printed Name <i>Donna Macedo</i>		
Signature <i>D. Macedo</i>		Date <i>5/10/02</i>
DECLARATION OF SHERRY X. GUO UNDER 37 C.F.R. § 1.132 Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket	LIFE008/LFS-101
	First Named Inventor	Sherry X. Guo
	Application Number	09/593,827
	Filing Date	June 13, 2000
	Group Art Unit	1623
	Examiner Name	M. Chaudhry
	Title	<i>Compositions Containing a Urea Derivative Dye for Detecting an Analyte and Methods for Using the Same</i>

#41/2
Supp
9/12/02

Dear Sir:

1. I, Sherry X. Guo, declare and say I am a resident of the State of California. My residence address is 2651 Mignon Drive, San Jose, CA 94086.

2. A copy of my curriculum vitae is attached (Attachment 1). I am skilled in the field of reagent detection. I am co-inventor of the claims of the above-identified patent application.

3. I have read the Office Action dated March 8, 2002 in this application and understand that the Examiner has rejected pending claims 1-23 on the basis that the claims are anticipated by U.S. Patent No. 5,972,294 (issued to Smith et al.), and has rejected claims 24-27 on the basis that the claims are obvious over U.S. Patent No. 5,972,294. It is also my understanding that this rejection

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is based on the assertion that the patent inherently teaches that a composition comprising the dye 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine and a nylon membrane would necessarily be storage stable as recited in the claimed invention.

4. The following experiments were conducted by me or under my direction.

5. **Preparation of Test Strips Coated with a Peroxide Producing Signal Producing System Including DA-67 on a Nylon Membrane.** A One Touch CH Nylon membrane was cut into strips of $1\frac{1}{4}$ " wide and 12 " long, and the membrane strip was first coated with the A dip solution and then with the B dip solution (ingredient and concentration specified in the following table). After each coating, the membrane was dried in hot air oven for 10 minutes at 55°C . The coated membrane was stuck to a 2 "x12 " Melinex support, which has a 5 mm diameter circular hole opening every quarter inch along its length for color measurement. The Melinex also has two stripes of $\frac{3}{8}$ " wide adhesive printed on top and bottom of holes. The membrane was laminated in the way that it completely covers the holes on Melinex. A layer of sample spreading Porex (1 "x12 ") was further laminated on top of membrane by adhesive printed on Melinex. The whole assembly was then cut into $\frac{1}{4}$ " wide strips.

A dip formulation	
Ingredient	Concentration
Ketoamine oxidase	206U/ml
Horseradish peroxidase	1mg/ml
Mannitol	4%
Poly(vinylpyrrolidone) (PVP), MW=360K	1%
EDTA	5mM
buffer	0.1M sodium phosphate
pH	7.5
B dip formulation	

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A dip formulation	
Ingredient	Concentration
DA-67	1.5mM
solvent	70% methanol

6. **Detection of Hydrogen Peroxide using Test Strips Coated with a Peroxide Producing Signal Producing System Including DA-67 on a Nylon Membrane.** To demonstrate the feasibility of color development on strips coated with stabilized DA-67 dye, a One Touch ®Nylon membrane was coated with a solution containing 2.5mM DA-67, 1mg/ml HRP and 1% PVP (MW=360K) in 0.5M pH 8.0 phosphate buffer. The membrane was then stuck to Melinex support, covered with Porex and cut into testing strips as described in example 2. Ten μ L volumes of various concentrations of H_2O_2 solutions were dropped on the strips respectively, and the color formation was monitored using a Macbeth reflectometer. To compare the detection sensitivity of DA-67 dye with that of the most commonly used dye for H_2O_2 , TOOS-4AP, a One Touch ®Nylon membrane was coated with a solution containing 5mM TOOS, 5mM 4AP, 1mg/ml HRP and 1% PVP (MW=360K) in 0.02M PBS, pH 7.4. The membrane was then used to prepare test strips as described above and tested with H_2O_2 using the method described above for DA-67 coated strips. The results were plotted in figure 3 (Attachment 2).

7. **Testing of Storage Ability of Test Strips Coated with a Peroxide Producing Signal Producing System Including DA-67 on a Nylon Membrane.** Test strips prepared as described above were stressed under various temperatures for various lengths of time. Exemplary stress conditions were 37°C for 1 month, 45°C for 2 weeks, and 56°C for one week. Under all conditions tested, the DA-67 coated nylon membrane color remained unchanged, i.e., DA-67 was not oxidized.

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8. **Preparation of Test Strips Using a Membran Other than Nylon Membrane.**

The above experiments were also performed with DA-67 coated on a hydrophilic polysulfone membrane and on a cellulose filter paper membrane. When coated with DA-67 and horseradish peroxidase, the membrane quickly turned blue after drying in a 56°C oven. Thus, DA-67 was oxidized in the absence of added H₂O₂ solution.

9. **Conclusion.** The above experiments demonstrate that DA-67 is storage stable on nylon, but is not storage stable on polysulfone. Moreover, the storage stability of the combination of DA-67 and a nylon matrix was wholly unexpected and was not predictable from the teaching of U.S. Patent No. 5,972,294.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code, and that such will false statements may jeopardize the validity of the application or any patent issuing thereon.

05-09-02
Date

Sherry X. Guo
Sherry X. Guo

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Summary

- Ph. D in Bioanalytical Chemistry with more than 5 years' industrial experience as research scientist in R&D of diagnostic companies
 - Expertise in design of new assay platforms
 - Experienced in all phases of new assay development for automatic analyzers
 - Insightful knowledge and hands-on skills in various analytical methods
-

Educational History

Ph.D in Bioanalytical Chemistry, 1996, Department of Chemistry, University of Michigan, Ann Arbor, MI. Research Advisor: Prof. Mark E. Meyerhoff
M.S. in Chemistry, 1994, Department of Chemistry, University of Michigan, Ann Arbor, MI.
M.S. in Analytical Chemistry, 1991, Department of Chemistry, Xiamen University, Xiamen, Fujian, P.R. China.
B.S. in Chemistry, 1988, Department of Chemistry, Xiamen University, Xiamen, Fujian, P.R. China.

Research & Development Experience

1996-present, LifeScan Inc., Milpitas, CA, Sr. Research Scientist

Significantly reduced the testing time of an electrochemical based glucose measurement technology that is in the developmental stage. Successfully completed the feasibility study of sample fill-detect feature implemented in the same blood glucose monitoring system. Characterized critical raw material and help to set raw material specifications for such product under development.

Established the feasibility an all-in-one-step enzymatic dry reagent assay for glycated serum proteins in whole blood sample.

Demonstrated the feasibility of a homogeneous electrometric immunoassay for hemoglobin A1C in whole blood sample via preparation of ligand-electroactive label conjugate and amperometric detection method.

March, 96-Oct, 96, Diagnostic Products Corporation, Los Angeles, CA, Research Scientist

Developed a commercialized solid-phase chemiluminescent enzyme immunoassay for osteoporosis marker, deoxy pyridinoline.

Developed a solid-phase chemiluminescent enzyme immunoassay for steroid hormone, androstenedione.

Incorporated with other scientist to develop a commercialized solid-phase chemiluminescent enzyme immunoassay for Vitamin B12.

1991-1996, University of Michigan, Ann Arbor, MI, doctoral graduate student

Developed a novel homogeneous, lectin-based, enzyme-linked binding assay for probing carbohydrate structures of glycoproteins, via the synthesis of a series of enzyme-saccharide conjugates by combining of organic and enzymatic methods.

Applied the above assay system to detect the type and relative amount of specific carbohydrate structures in various intact glycoproteins, such as human IgA, low density lipoprotein (LDL), high density lipoprotein (HDL) and sheep red blood cell surface glycoproteins.

Developed a new rapid homogeneous enzyme-linked binding assay for studying glycosaminoglycan-macromolecule/peptide interactions.

1989-1991, Xiamen University, Xiamen, Fujian, China, graduate student
Designed a new solid powder sampler for ICP Atomic Emission Spectrometer.

1988, Xiamen University, Xiamen, Fujian, China
Developed a chemiluminescence spectrometric method for determination of gold concentration in mineral samples (Undergraduate research project).

**Other
Experience**

Member of a Process Excellence team that is responsible for writing guidelines for technology evaluation (performance check) during both feasibility stage and product development stage, 2001, LifeScan Inc.
Received some DOE, Design control, Document Control trainings, 1996-2001, LifeScan Inc.
Graduate Teaching Assistant, 09/91-12/92, Dept. of Chem., Univ. of Michigan
Graduate Teaching Assistant, 09/89-02/90, Dept. of Chem., Xiamen University

Skills

Intensive experience in the following areas: 1) formulation and strip design for various dry reagent assay formats; 2) assay scheme design for various solution phase assays including immunoassays; 3) Method development for automatic analyzers; 4) Preparation of ligand-label conjugates such as enzyme-ligand conjugates.

Hands-on experience with various analytical methods such as HPLC, TLC, GC, NMR, UV-Vis, Fluorescence, Atomic Absorption Spectrometry, Gel-filtration, Ion-exchange and Affinity Chromatography

Honors

Moses-Gomberg Scholarship, 1992, University of Michigan
Barbour Scholarship, 1995, University of Michigan

Publications

1. Zhang, B. and Guo, X., "Algorithm for a six-second electrochemical based glucose test", Lifescan invention disclosure, Dec., 2001.
2. Zhang, B. and Guo, X., "Algorithm for a five-second or less electrochemical based glucose test", Lifescan invention disclosure, Dec., 2001.
3. Kermani, M., Teodorczyk, M and Guo, X., "Determination of sample volume adequacy in biosensor devices", US patent application, filed in Oct, 2001.
4. Guo, X. "A six-second test method for detecting blood glucose using an electrochemical sensor", Lifescan invention disclosure, April, 2001.
5. Guo, X. et al "A six-second test method for detecting hematocrit and glucose in blood using an Electrochemical Sensor" Lifescan invention disclosure, March, 2001
6. Guo, X and Leong, K, "Compositions Containing A Urea Derivative Dye For Detecting An Analyte And Methods For Using The Same", US patent application, filed in May 2000.
7. Guo, X., "Homogeneous amperometric immunoassay for determination of Hemoglobin A1c" Lifescan invention disclosure, April, 1998
8. Guo, X. and Meryerhoff, M. E., "Synthesis of N-acetylneuraminyl-alpha-2, 3 (6)lactose-malate dehydrogenase conjugate for detecting sialic acid terminal groups on glycoproteins via

homogeneous lectin-based enzyme-linked binding assay," *Appl. Biochem. Biotechnol.*, 1997, **68**, 41

9. Guo, X.; Meyerhoff, M. E. and Yang, Y.C. "Homogeneous Enzyme-Linked Binding Assay For Studying Glycosaminoglycan-Macromolecule Interactions," *Anal Biochem*, 1996, **235**, 153

10. Buckwalter, J.; Guo, X. and Meyerhoff, M.E., "Dual Enzyme Labels for Simultaneous Heterogeneous Enzyme-Linked Competitive Binding Assays," *Anal. Chim. Acta*. 1994, **298**, 11

11. Wang, Z. B., Guo, X., "Determination of Trace Level of Gold in Mineral Samples by Chemiluminescent Method," *Analysis of Minerals and Metals*, 1989, **20**, 56

Status

U.S. permanent resident.



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TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	09/593,827
		Filing Date	June 13, 2000
		First Named Inventor	GUO, SHERRY X.
		Group Art Unit	1623
		Examiner Name	CHAUDHRY, MAHREEN F.
Total Number of Pages in This Submission	19	Attorney Docket Number	LIFE-008
ENCLOSURES (check all that apply)			
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm or Individual Name	BRET E. FIELD, Reg. No. 37,620		
Signature			
Date	May 10, 2002		

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: May 10, 2002.	
Typed or printed name	Donna Macedo
Signature	
Date	May 10, 2002

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